In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-792V

Filed: January 4, 2023

HEATHE HELLER and JENNA HELLER, parents of H.H., a minor, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Ruling on Remand; Type I Interferonopathy; Significant Aggravation

Margaret Guerra, Margaret M. Guerra, Attorney at Law, Fort Worth, TX, for Petitioners
Tyler King, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON REMAND GRANTING ENTITLEMENT[1]

Oler, Special Master:

On July 27, 2015, Heathe Heller ("Mr. Heller") and Jenna Heller ("Ms. Heller") (collectively "Petitioners") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program") alleging, in part, that as a result of his October 17, 2013 influenza and Prevnar vaccinations and his October

[1] This Ruling will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Ruling's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Ruling will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

23, 2013 vaccination with Pentacel, H.H. experienced either the onset or the significant aggravation of his degenerative neurologic disorder.

I held an entitlement hearing on January 22, 2020. In a decision issued on April 15, 2022, I found preponderant evidence in support of the fact that H.H. has "a genetic type I interferonopathy that is either [Aicardi-Goutières Syndrome ("AGS")] or AGS-like." *Heller v. Sec'y of Health & Hum. Servs.*, No. 15-792V, 2022 WL 16575744 at *51 (Fed. Cl. Spec. Mstr. Apr. 15, 2022) ("Entitlement Decision"). I further found that the Pentacel vaccine did not significantly aggravate H.H.'s type I interferonopathy. *Id.* at *61. Petitioners sought review and the Court vacated my decision and remanded the case to me for further evaluation. *Heller v. Sec'y of Health & Hum. Servs.*, 162 Fed. Cl. 621 (2022) ("Remand Opinion"). For the reasons discussed below, I find that Petitioners are entitled to compensation.

I. Brief Procedural History

On July 27, 2015, Heathe and Jenna Heller, on behalf of their minor son, H.H. filed a petition seeking compensation under the Vaccine Act, alleging that H.H. suffered from dystonia and encephalopathy as a result of the influenza ("flu") and Prevnar vaccinations he received on October 17, 2013, and/or the DTaP-IPV-Hib ("Pentacel") vaccine he received on October 23, 2013. Pet. at 1.

My Entitlement Decision narrowed the issues present in the case. I determined that the October 17, 2013 flu and Prevnar vaccines did not impact H.H., a determination that the Court upheld. Entitlement Decision at *51; *see also* Remand Opinion at 638. I further found that the onset of H.H.'s AGS-like disease began shortly before his receipt of the Pentacel vaccine on October 23, 2013. Entitlement Decision at *51. As a result, the proper analysis for the claim was one of significant aggravation. *Id.*

In analyzing the case pursuant to *Loving v. Secretary of Health & Human Services*, I determined that H.H.'s receipt of the Pentacel vaccine did not significantly aggravate his neurologic condition. 86 Fed. Cl. 135 (2009) (citing *Althen v. Sec'y of Health & Hum. Servs*, 418 F.3d 1274 (Fed. Cir. 1995)). Specifically, I found that Petitioners did not present 1) a reliable medical theory explaining how the Pentacel vaccine can cause the significant aggravation of a type I interferonopathy; 2) preponderant evidence that H.H.'s Pentacel vaccine did cause a significant aggravation of his pre-existing condition; or 3) evidence of a proximate temporal relationship between the significant aggravation of H.H.s vaccination and his condition. Entitlement Decision at *55, *58, *61.

With respect to *Loving* prong four/*Althen* prong one, I found that Petitioners' theory that vaccination can cause persistently elevated levels of interferon alpha unpersuasive. Entitlement Decision at *54-55. While Petitioners are not required to present medical literature or epidemiological evidence, their theory must be supported by a reputable medical or scientific explanation, and I did not believe Petitioners presented such a theory in this case. *Id.*

Regarding *Loving* prong five/*Althen* prong two, I also found that Petitioners had not demonstrated by preponderant evidence that the Pentacel vaccine did significantly aggravate

H.H.'s type I interferonopathy. Entitlement Decision, at *58. H.H. received the Pentacel vaccine on October 23, 2013, after he had already been experiencing heel cord tightness which was a physical sign of his type I interferonopathy. *Id.* at *23. Therefore, Petitioners had the burden of demonstrating that H.H.'s deterioration was caused in part by the Pentacel vaccine he received, and I found that Petitioners did not preponderantly do so. *Id.* at *58.

Lastly, as to *Loving* prong six/*Althen* prong three, I found that the onset of H.H.'s interferonopathy occurred around the time of his October 17, 2013 vaccinations and that Petitioners' evidence pertaining to timing did not support their contention that the Pentacel vaccine caused or significantly aggravated H.H.'s condition. Entitlement Decision at *51, *61.

On May 16, 2022, Petitioners file a Motion for Review of my Entitlement Decision. ECF No. 122.

After the parties filed briefs and had oral argument on September 13, 2022, the Court issued an opinion on October 13, 2022[3] remanding this case back to me. ECF No. 134. The Court's Remand Opinion held (1) that I erred by mischaracterizing H.H.'s interferonopathy as AGS or AGS-like because this finding "effectively eliminated the possibility" of a conclusion that the vaccine had significantly aggravated H.H.'s condition; and (2) that my findings that Petitioners had failed to carry their burden under *Loving* prongs four, five, and six were arbitrary and capricious. Remand Opinion at 644, 652, 655, 657. The Court ultimately remanded the case back to me to determine whether Petitioners can satisfy *Loving* prongs four, five, and six and demonstrate that the Pentacel vaccine did significantly aggravate H.H.'s type I interferonopathy. *Id.* at 657.

After the Court remanded the case to me, I held a status conference on October 19, 2022, and instructed Respondent to show cause as to why I should not rule in favor of Petitioners, given the Court's decision. ECF No. 135. I gave the parties an opportunity to brief this matter. Respondent filed his brief on November 18, 2022. ECF No. 138 ("Resp't's Br."). Petitioners filed a reply on December 17, 2022. ECF No. 139 ("Pet'rs' Br."). This matter is now ripe for a determination.

II. The Parties' Arguments

A. Respondent

In his response to my show cause order, Respondent maintained that Petitioners have failed to provide preponderant evidence that the Pentacel vaccine significantly aggravated H.H.'s interferonopathy. Resp't's Br. at 1. Respondent disagreed with the Court that my findings that H.H. experienced AGS or an AGS-like interferonopathy "foreclosed a finding of significant aggravation," and that I erred in my analysis of *Loving* prong four. *Id.* at 3.

[3] The Remand Opinion was issued on October 13, 2022 and the parties were given 14 days to file a Motion for Redaction. Neither party moved for redactions. The Court reissued the opinion on October 31, 2022 in its original form. ECF No. 136.

As to *Loving* prong four/*Althen* prong one, Respondent argued that Petitioners have not provided a "sound and reliable medical or scientific explanation" for significant aggravation for two reasons. Resp't's Br. at 3-4. First, Dr. Steinman failed to explain how activation of the NALRP3 inflammasome is linked to the development of interferonopathy. *Id.* at 4. Second, Dr. Steinman's theory was supported by medical literature discussing experimental autoimmune encephalomyelitis (EAE), which is an injury entirely different from interferonopathy. *Id.* Respondent argued that Petitioners' evidence does not pertain to H.H.'s actual injury, and thus does not satisfy the preponderant evidence standard for *Loving* prong four. *Id.*

As to *Loving* prong five/*Althen* prong two, Respondent contended that Petitioners have not met their burden to provide preponderant evidence that the Pentacel vaccine did in fact significantly aggravate H.H.'s interferonopathy. Resp't's Br. at 5. First, Respondent argued that the opinions of H.H.'s treating physicians that his injury was aggravated by the vaccine are rebuttable and not dispositive. *Id.* Respondent further stated that my decision to credit the opinion of Respondent's expert over that of Petitioners' expert was appropriate. *Id.* at 6.

Finally, Respondent argued that Petitioners have not met their burden under *Loving* prong six/*Althen* prong three because they failed to marshal preponderant evidence that the significant aggravation of H.H.'s interferonopathy occurred within a medically acceptable timeframe after vaccination. Resp't's Br. at 6. Respondent maintained that Petitioners have not shown that three weeks after vaccination is a medically acceptable onset interval. *Id.* at 7. Respondent pointed out that Dr. Steinman relied on medical literature discussing Guillain-Barré syndrome (GBS) and acute disseminated encephalomyelitis (ADEM), both of which are entirely different injuries from an interferonopathy. *Id.*

B. Petitioners

In their response brief, Petitioners urged that Respondent has failed to show cause as to why I should not find for Petitioners. Pet'rs' Br. at 1. Petitioners argued that the Court's analysis "demonstrate[s] that Petitioners met their burden of proof for 'significant aggravation' by the Pentacel vaccine under *Loving* prongs four, five, and six." *Id.* at 2.

As to *Loving* prong four, Petitioners asserted that they have met their burden and that Respondent's expert failed to rebut the medical literature provided by Petitioner's expert. Pet'rs' Br. at 3. As to prong five, Petitioners echoed the Court's observation that Dr. Marks, H.H.'s treating physician, opined that H.H.'s condition was the result of the vaccines he received. *Id.* As to prong six, Petitioners argued that they provided sufficient evidence to meet their burden and repeated the Court's opinion that my decision did not provide enough analysis on this point. *Id.*

III. Analysis

In any remanded case, the special master is bound by the determinations of the Court on matters of law and fact. *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952, 959 (Fed. Cir. 2011) (quoting *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (Fed. Cl. 1998)). Petitioners challenged my analysis of H.H.'s clinical presentation/diagnosis and my legal conclusions as to prongs four, five, and six of the *Loving* analysis. Remand Opinion at 632.

A. *Loving* Prong Four

Under *Loving* prong four, a petitioner must provide a "reputable medical theory" that the vaccine can significantly aggravate the type of injury in question. *Loving*, 86 Fed. Cl. at 144; *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The theory must be based on "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). The theory must be "legally probable, not medically or scientifically certain." *Id.* at 548-49.

In my entitlement decision, I noted the lack of medical literature exploring a causal link between the flu, pneumonia, or Pentacel vaccines and type I interferonopathy. Entitlement Decision at *55. I analyzed the medical literature submitted by Dr. Steinman and found that it did not supply "a sound and reliable medical theory explaining how vaccination causes the chronic overproduction of interferon." *Id*. Accordingly, I found that Petitioners had failed to carry their burden under *Loving* prong four. *Id.*

The Court stopped short of finding that I erred in my assessment of the medical literature. Remand Opinion at 650. However, the Court's *Loving* prong four analysis made it clear that the Court finds the medical literature upon which Dr. Steinman relied more persuasive than I did. *Id.* at 646-52. The Court discussed each of the seven studies cited by Dr. Steinman in support of his causal theory. *Id.* The first article, Fadugba, concluded that DTaP vaccination results in an increase in gamma interferon. *Id.* at 646. The Court determined that this particular point discussed in Fadugba "carries significant weight in favor of petitioners satisfying their burden" under *Loving* prong four. *Id*. The Court further discussed the other six studies, similarly noting that each of them "add[] further support" or "weigh in favor" of petitioners providing preponderant evidence in support of the fourth *Loving* prong. *Id.* at 647-49. Ultimately, the Court concluded that the cited studies "cumulatively carry <u>significant weight</u> in favor of petitioners satisfying their burden." Remand Opinion at 651 (emphasis added).

In re-analyzing Petitioners' proffered evidence in support of their causal theory through this lens, I conclude that Petitioners have provided preponderant evidence in support of *Loving* prong four. Petitioners' evidence supports the contention that the DTaP vaccine can trigger the production of interferons. Furthermore, Dr. Steinman's opinion and the Li article support Petitioners' position that the Pentacel vaccine activates the NALRP3 inflammasome, which, according to Dr. Steinman "plays a key role in inducing interferonopathies." First Steinman Rep. at 12. Finally, Rodero and Crow question whether vaccination is a disease trigger for AGS. While the continued high level of interferon production H.H. exhibited is not described in the medical literature provided, I nevertheless find that Petitioners have provided a "reputable medical theory" causally linking the Pentacel vaccine to significant aggravation of H.H.'s type I interferonopathy. *Pafford*, 451 F.3d at 1355-56. In so concluding, I am cognizant that "[t]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. Accordingly, *Loving* prong four is satisfied.

B. *Loving* Prong Five

Loving prong five/*Althen* prong two requires Petitioners to provide a logical sequence of cause and effect demonstrating that the Pentacel vaccination did cause a worsening of H.H.'s pre-existing interferonopathy. *Althen*, 418 F.3d at 1278; *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009); *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

In my decision on entitlement, I found that both Dr. Hollis and Dr. Marks were unpersuasive experts, in part because they either did not articulate a theory of causation (Dr. Hollis) or because their proffered theory was unreliable (Dr. Marks). Entitlement Decision at *56-58. At the entitlement hearing, Dr. Marks was unable to articulate a theory as to how the vaccines can cause a significant aggravation of a type I interferonopathy, espousing the now-abandoned theory of molecular mimicry, and repeatedly testifying that he was not an expert in vaccines. In fact, his proffered causation theory was, in my view, so deficient that I informed Petitioners' counsel they could not meet their burden as the record currently stood, and gave Petitioners the opportunity to hire another neurologist and file post-hearing expert reports.

The Court found that I erred in discrediting H.H.'s treating physicians, Drs. Marks and Hollis, who both opined that the vaccines caused H.H.'s condition. Remand Opinion at 655. The Court stated that I improperly considered Dr. Hollis' lack of a theory, and Dr. Marks' molecular mimicry causation theory in evaluating the credibility of those experts concerning their opinion that the vaccines "did cause" a significant aggravation of H.H.'s condition "because prong five does not require a treating physician to opine on a medical theory to find their testimony persuasive—only prong four requires opinion on a medical theory." *Id.* I have reconsidered my evaluation of Dr. Hollis and Dr. Marks in light of this statement. In so doing, I find that Drs. Marks and Hollis' opinions regarding vaccine causation provide preponderant evidence that H.H.'s disease process was significantly aggravated by the Pentacel vaccine.

Dr. Hollis opined that H.H.'s "severe and rapid developmental regression is unusual for a previously healthy child… his rapid decline can be attributed to receiving the vaccinations on October 17, 2013 and October 23, 2013." Ex. 66 at 3. In evaluating this statement without considering the fact that Dr. Hollis did not provide a theory as to how this occurred, I find that Dr. Hollis' opinion constitutes strong evidence in support of *Loving* prong five. She was H.H.'s pediatrician during his rapid decline post-vaccination and saw the disease progression take place.

Dr. Marks opined that H.H. experienced a persistent immune response since his vaccination; H.H. "had persistent elevations of an immunologic marker usually seen in the context of viral infections more than bacterial infections." Tr. at 158-59. Dr. Marks further opined that it is more likely than not that H.H.'s condition was significantly aggravated by the Pentacel vaccine, rather than H.H. deteriorating due to a typical AGS pathology. *See generally id.* at 161. Dr. Marks also noted that there is a "lack of any other explanation for why [H.H.] has developed severe and rapidly progressing dystonia with encephalopathy at his age," and concluded that the Pentacel vaccine was "the most likely trigger for him to develop rapidly progressing dystonia with encephalopathy to this degree." Ex. 67 at 3-4. In considering this testimony without evaluating the

"can cause" element of his opinion, I find that Dr. Marks' expert opinion provides additional and substantial weight in support of Petitioners' significant aggravation claim.

In view of my reevaluation of the weight of Drs. Hollis's and Marks's opinions regarding H.H.'s rapid deterioration after vaccination and Dr. Steinman's theory regarding how the Pentacel vaccine could have contributed to the significant aggravation of H.H.'s condition, I find that Petitioners have provided preponderant evidence that the Pentacel vaccine did significantly aggravate H.H.'s type I interferonopathy.

C. *Loving* Prong Six

The final prong of the *Loving* analysis requires Petitioners to demonstrate a "proximate temporal relationship" between the significant aggravation of H.H.'s condition and the vaccine. *Loving*, 86 Fed. Cl. at 144; *see also Althen*, 418 F.3d at 1278. Petitioners must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The proximate temporal relationship requirement has two components. First, Petitioners must establish the "timeframe for which it is medically acceptable to infer causation" and second, they must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

In my entitlement decision, I found that Petitioners had failed to meet their burden under both components of *Loving* prong six. Having previously found that onset of H.H.'s condition occurred "close-in-time to his October 17, 2013 vaccinations and before he received the Pentacel vaccine," I found that Petitioners had not established that H.H.'s condition began or was significantly aggravated three weeks after the Pentacel vaccine as Dr. Steinman claimed. Entitlement Decision at *59-61. I also found that Petitioners had not established that three weeks was a medically acceptable timeframe to infer causation because the medical literature upon which Dr. Steinman relied pertained to GBS and ADEM, conditions dissimilar to H.H.'s injury, and conditions caused by a different immune-mediated mechanism than the one espoused by Dr. Steinman. *Id.* at *60-61.

In his decision remanding this case to me, the Court found that I had not considered Dr. Steinman's significant aggravation analysis and that I "did not provide an analysis to discuss the timeline of H.H.'s injuries or whether H.H.'s injuries were significantly aggravated." Remand Opinion at 657. The Court further found that I had failed to articulate a rational basis for my decision and that my decision was unsupported by the record. *Id.* The Court left the determination as to whether Petitioners have met the requirements of *Loving* prong six to me. *Id.*

Before re-analyzing these issues, it is important to clarify one aspect of Dr. Steinman's opinion. In my Entitlement Decision, I concluded that Dr. Steinman opined "H.H.'s disease course began three weeks after his receipt of the Pentacel vaccine." Entitlement Decision at *59. This determination was based on several of Dr. Steinman's statements in his expert reports. For example, Dr. Steinman opined that "[n]ot until three weeks after the Pentacel immunization on

October 23, 2013 was there any symptomatology related to an interferonopathy." First Steinman Rep. at 16. In support of *Althen* prong three, Dr. Steinman also stated "'A showing of a proximate temporal relationship between vaccination and injury' is met from similar studies on other neuroinflammatory conditions linking neuroinflammation and immunization, with onset at approximately 3 weeks post-Pentacel vaccine." *Id.* Dr. Steinman further opined: "Onset of significant deterioration occurred within about 3 weeks ***after*** the Pentacel immunization or four weeks from the influenza and Prevnar 13 immunizations." *Id.* at 8 (emphasis in original).[4]

Dr. Steinman's reliance on Schonberger to support his opinion further indicated to me that he was in fact opining that H.H.'s disease course was significantly aggravated three weeks after his receipt of the Pentacel vaccine. Schonberger demonstrates that the swine flu vaccine can cause GBS, a demyelinating disease of the peripheral nervous system. Schonberger found that "[t]he peak relative risks … occurred in weeks 2 and 3 after vaccination." Schonberger at 112.

It is notable, however, that Dr. Steinman also states that H.H.'s significant aggravation occurred "within three weeks" of his receipt of the Pentacel vaccine. *See, e.g.*, First Steinman Rep. at 15; Second Steinman Rep. at 3.

The Court found Dr. Steinman's use of the word "within" to indicate that significant aggravation began at some time during the three-week period following vaccination. Remand Opinion at 657 ("The Court remands and leaves the ultimate conclusion to the Special Master regarding whether there was a proximate-temporal relationship in light of Dr. Steinman's opinion stating aggravation would occur within three weeks and whether this theory satisfies *Loving* prong six."). Based on this instruction, I have re-analyzed *Loving* prong six and have assumed Dr. Steinman opined that the significant aggravation of H.H.'s interferonopathy began within three weeks of the Pentacel vaccine.

I first analyze whether Petitioners have provided a medically acceptable time frame such that significant aggravation of interferonopathy "within three weeks" after receipt of Pentacel can be inferred.

Respondent's expert, Dr. McGeady, disagreed with Dr. Steinman's proposed timeframe, opining that he would expect vaccine-induced excessive interferon production to result in central nervous system injury "sooner than several weeks following the immunizations." Second McGeady Rep. at 2. Dr. McGeady opined as follows:

> Type I interferons are produced by cells of the innate immune system upon activation by a variety of pattern recognition receptors. They detect molecular patterns that are prevalent in pathogenic organisms, but not found in mammals, and their detection leads, among other responses, to the generation of type I interferons

[4] Although Dr. Steinman used the phrase "within three weeks" here, when read in conjunction with the sentence's second clause, "or four weeks from the influenza and Prevnar 13 immunizations," his meaning appeared to be that onset of H.H.'s interferonopathy took place three weeks after Pentacel and four weeks after flu/pneumonia vaccines.

> (1).[5] Since this immune response is among the host's first to resist a potentially lethal infection, it is rapidly deployed, and type I interferons are present in measurable quantities within 12 hours following a viral exposure (2). In view of this kinetic pattern, and knowing that interferon production promptly decreases following a non-progressive provocation, it would be expected that an acute injury to the CNS due to excessive type I interferon would appear sooner than several weeks following the immunizations if vaccines are to be suspected as the initiating event.

Id. Although Dr. McGeady did not specify the appropriate temporal interval for vaccine-induced interferon production and subsequent CNS injury, he did note that "the Vaccine Injury Table stipulates a time of up to 72 hours for an encephalopathy as the period in which such an adverse event might be attributed to the DTaP component of Pentacel…" *Id.* at 3. Dr. McGeady's position that both interferon production and CNS injury following the DTaP component of the Pentacel vaccine occur within 72 hours of vaccination is consistent with other reported Vaccine Program cases which discuss cytokine-driven responses. *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 148 (2009) (noting that "warnings establish that adverse events occurring within seventy-two hours of [pertussis] vaccination are typical."); *Jimenez v. Sec'y of Health & Hum. Servs.*, No 17-1190V, 2021 WL 3179643, at *14 (Fed. Cl. Spec. Mstr. Jun. 23, 2021) (citing medical literature which notes that cytokine response occurs between 3 and 72 hours post vaccination); *Brunson v. Sec'y of Health & Hum. Servs.*, No 17-530V, 2020 WL 5755502, at *20 (Fed. Cl. Spec. Mstr. Sep. 3, 2020) (citing Petitioner's expert for the proposition that SIDS deaths typically occur within 72 hours of immune provocation, correlating with "peak post-vaccination cytokine production."); *Wolf v. Sec'y of Health & Hum. Servs.*, No 14-342V, 2016 WL 6518581, at *16 (Fed. Cl. Spec. Mstr. Sep. 15, 2016) (concluding that petitioner did not meet her burden, due, in part, to the fact that cytokine upregulation would be underway "in less than 72 hours," yet petitioners did not bring R.W. to the doctor until one month post vaccination). Although these opinions are not binding on me, they provide persuasive authority on this point.

It transpires, then, that Dr. McGeady's opinion and Dr. Steinman's are not mutually exclusive. Dr. Steinman opined that significant aggravation began "within" the first three weeks after vaccination, and Dr. McGeady's estimate of "sooner" than three weeks falls within that period. Taking the two opinions together, I conclude that locating the start of significant aggravation sometime within 72 hours of receiving Pentacel is medically reliable such that causation can be inferred.[6]

[5] Although Dr. McGeady indicated citation to medical literature, that literature was not listed in his report or filed into the record.

[6] For the reasons articulated in my original entitlement decision, I do not find Dr. Steinman's discussion of Schonberger or Bennetto & Scolding to be persuasive. The Schonberger article discusses a different vaccine, both articles discuss different injuries, and importantly, both refer to different mechanisms of disease initiation.

The medical records are sparse concerning the significant aggravation of H.H.'s condition immediately after his receipt of the Pentacel vaccine, as H.H. did not see a medical provider until his visit to Dr. Hollis on November 11, 2013. However, the parties did fill in some of these gaps through testimony. *See James-Cornelius v. Sec'y of Health & Hum. Servs.*, 984 F.3d 1374, 1380 (Fed. Cir. 2021) (concluding that "for many medical symptoms or events … the patient's or a parent's testimony may be the best, or only, direct evidence of their occurrence."). Ms. Heller and H.H.'s grandmother testified that, after receiving the Pentacel vaccine on a Wednesday, H.H. had a high fever and slept for much of the following weekend. Tr. at 18, 113. This testimony is supported by the affidavit of Angela Kleinhans, who averred that H.H. had a high fever the weekend after he received his vaccines. Ex. 92 at 2. Ms. Sewell, H.H.'s grandmother testified that H.H. slept "more than he ever had before." Tr. at 113. Dr. Marks testified that H.H.'s fever likely constituted a vaccine reaction, and that it was likely the onset of his disease process. *Id.* at 195. Dr. McGeady conceded that H.H.'s fever "could have been a reaction to the vaccine." *Id.* at 227. Ms. Heller described that the next week was Halloween week, and during that time, H.H. began dragging his right leg. *Id.* at 18-19. Mr. and Ms. Heller and H.H.'s grandmother agreed that by Halloween, H.H. was noticeably worse, dragging his leg and falling frequently while trying to stand. *Id.* at 19-20, 99, 114. Sheri Huling's letter, filed after the entitlement hearing, supports this position. Ms. Huling stated that H.H. had right heel cord tightness soon before he received his Pentacel vaccine on October 23, 2013. Ex. 102 at 1. Ms. Huling further stated that she saw H.H. on Halloween and "noted worsening in his tightness in [his] right heelcord." *Id.* (emphasis added). Ms. Huling further averred that she saw H.H. fall once while sitting and once while standing. *Id.* Ms. Kleinhans remarked that H.H. got sick "and he was never the same again." Ex. 92 at 2. The statements of Ms. Huling, Ms. Kleinhans, H.H.'s grandmother, and Petitioners are consistent with Dr. Hollis's note at the November 11, 2013 appointment that H.H.'s development had regressed "in the last month." Ex. 49 at 41.

The lack of contemporaneous medical record documentation covering the three-week period following Pentacel vaccination makes it difficult to pinpoint the specific date on which significant aggravation began. However, I find that there is preponderant evidence in the record that the significant aggravation of H.H.'s condition began with systemic symptoms a few days after receiving the Pentacel vaccine and continued to progress over the following weeks with worsening heel cord tightness, H.H.'s dragging of his right leg, and his progressive inability to sit unassisted, stand without falling, or crawl. This timeline is consistent with Petitioners' medical theory. Petitioners have presented preponderant evidence in support of *Loving* prong six.

VI. CONCLUSION

For the foregoing reasons and in light of the Court's Remand Opinion, I find that Petitioners have satisfied each of the *Loving* prongs. Accordingly, Petitioners are entitled to compensation under the Vaccine Act. An order regarding damages shall issue.

The Clerk's Office is instructed to provide this Ruling to the assigned judge. *See* Vaccine Rule 28.1(a).

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master